DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

February 24, 1999

WARNING LETTER NYK 1999-33

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. James L. Flacke, President
Home Therapy Equipment Inc.
2037 Route 9
Round Lake, New York 12151

Dear Mr. Flacke:

During an inspection of your medical gas manufacturing facility conducted December 21, 1998 through January 8, 1999, our investigator documented deviations from the Current Good Manufacturing Practice regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 and 211). These deviations cause your drug products, Oxygen, Refrigerated Liquid, USP (ORL), and Oxygen, USP to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). The deviations noted by the investigator include, but are not limited to, the following:

1. Failure to test incoming bulk ORL for identity prior to filling home units as required by 21 CFR 211.165(a). For example, your firm did not perform identity testing on incoming bulk ORL from at least September 1, 1998 to December 21, 1998.

2. Failure to properly calibrate the Oxygen Analyzer according to the manufacturer's directions, i.e. to use the calibration gases specified, as required by 21 CFR 211.160(b)(4). For example, up until the date of the inspection, your firm did not use Nitrogen NF with a minimum potency of 99.9% for the "zero" step in the calibration of its [redacted] as directed by the manufacturer.

3. Failure to ensure each individual engaged in the manufacture of ORL has the education, training, and experience, or any combination thereof, to enable that person to perform assigned functions as required by 21 CFR 211.25(a). For example, the individual reviewing the oxygen gas transfilling batch records does not know the acceptable purity for Oxygen, USP.

4. Failure to follow written production and process control procedures as required by 21 CFR 211.100(b). For example, your firm does not perform identity testing on incoming ORL received from its suppliers; it does not complete Liquid Oxygen Control Logs (batch records); and it does not review Liquid Oxygen Control Logs (batch records) as required by its written procedures for ORL operations.

5. Failure to retest ORL in home vessels for identity after repair of home vessels and prior to distribution as required by 21 CFR 211.87.

Our office is aware of corrective measures your firm initiated during the inspection to correct some of the aforementioned violations. However, we will reserve judgement of the adequacy of these actions until we receive a written response from your firm addressing additional steps you have taken to correct the violations and to prevent future violations.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure all drugs manufactured and distributed by your firm meet the requirements of the Act, and the regulations promulgated thereunder. Federal agencies are advised of all warning letters regarding drug products so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to correct these deviations may result in regulatory action without further notice. Possible regulatory actions include seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Your response may be directed to Lisa M. Utz, Compliance Officer, at the above address. Ms. Utz can be reached by telephone at (716) 551-4461, ext. 3165.

Sincerely,

Brenda J. Holman
District Director